

## **DETAILED ACTION**

### ***Acknowledgements***

1. This office action is in response to the reply filed on 12/18/2007.
2. In the reply the applicant amended claims 1, 2, 3, 6, and 7.
3. Thus, claims 1-10 are pending for examination.

### ***Election/Restrictions***

4. Applicant's election with traverse of Group I, claims 1-10 during a teleconference on July 20, 2007, is acknowledged. The traversal is on the ground(s) that the claims in Group I and Group II contain the same limitations and scope as each other with respect to each and every claimed element, and that despite the different classification of Group I and Group II, no burden is placed on the Examiner to search for product and process of use claims. This is not found persuasive because as noted in the last office action, the product as claimed can be used in a materially different process of using that product. The product can be used, for example, by applying the color-coded stickers of the immunization identification system on to different binders or notebooks that belong to the same category. The product is simply a series of stickers; nothing about the stickers makes them unique to immunization identification.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall (US 2004/0158186) in view of Walsh (US 6,464,136).

In regards to claim 1, Hall describes an adhesive bandage that can be used for the identification of a vaccine administered at an injection site. In Hall (page 2, claim 11), a method of vaccination is described comprising the administration of a vaccine by injection into a recipient at a vaccination site and the application of adhesive bandage to the vaccination site. The exposed surface of the bandage displays indicia that identify the vaccine that was administered. While not explicitly stated by Hall, a syringe must be intrinsically filled with an immunization dosage in order to administer a vaccine. Hall does not teach the application of an adhesive-backed strip to a syringe and the application of another adhesive-backed strip to a medical chart of a patient. However, Walsh further describes a method for the verification of the identity of a patient

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undergoing medical treatment. In the claims of Walsh (column 33, lines 61-67 to column 34, lines 1-11), a method for the identification of a patient and their treatments is described comprising the use of a syringe and the application of labels to drug containers, syringes, and to at least one “patient identification member.” The “patient identification member” can be a patient treatment chart. In the specification of Walsh (column 28, lines 32-34), the syringe is filled with an appropriate drug and a label is placed on the syringe. Concerning the “patient identification member” of Walsh (column 34, lines 7-11), it can be a “patient treatment chart,” which according to a person having ordinary skill in the art, is synonymous to the “medical office chart of the patient.” In the specification of Walsh (column 28, lines 23-27), printed on the label is the name of the patient and a barcode that references treatments. It would have been obvious to a person having ordinary skill in the art to incorporate the teachings of Walsh to the teachings of Hall because doing so would further facilitate in the verification of a patient who is undergoing medical treatments, such as the administration of immunizations, and avoid unnecessary medical error.

In regards to claim 2, which is dependent on claim 1, it describes the same method of immunization identification as claim 1 but is used for a second immunization dosage. Hall (page 3, claim 13) suggests the administration of at least two vaccines to one patient by the statement that “at least two different vaccines are separately and concurrently administered to the intended recipient with separate adhesive bandages being applied to each vaccination site.” To a person having ordinary skill in the art, with the teachings of Hall and Walsh, it would be obvious that the method for the

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administration of the first immunization dosage and application of the labels to the first immunization apparatuses is the same as the method for the administration of the second immunization dosage and application of labels to the second immunization apparatuses. These methods aid in the tracking of more than one immunization to avoid medical error.

In regards to claim 3, Hall does not teach the application of a strip to a home chart of the patient, but to a person having ordinary skill in the art, it can be inferred from the teachings of Walsh (column 34, lines 7-11) that a home chart contains the same information about the history of a patient's medical treatments as the "patient treatment chart." Walsh (column 33, lines 65-67) also teaches of a "plurality of identical patient identifier carrying labels" that can be applied to "a patient identifying member" such as "a patient treatment chart" (column 34, lines 7-11). It would be obvious to a person having ordinary skill in the art to apply these teachings of Walsh to those of Hall in order for a patient to have the ability to keep track of immunizations that have been administered to them through a chart and to avoid medical error.

In regards to claim 6, Hall does not teach of a series of stickers with a common first indicia that correspond to first immunization apparatuses, but Walsh (column 33, lines 65-67) teaches that the identification labels are a "plurality of identical patient identifier carrying labels." It would be obvious to a person having ordinary skill in the art that if the labels are identical, they have a common indicia. Furthermore, it would be obvious to apply these teachings of Walsh to those of Hall in order to set up a group of

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similar labels that can be applied to all of the apparatuses used in a single immunization procedure.

In regards to claim 7, which is dependent on claim 6, it requires a “common second indicia” for the second immunization. As cited above for claim 6 with Walsh (column 33, lines 65-67), it would be reasonable to expect that the second immunization would also have a set of similar identification labels in comparison to those of the first immunization. As cited above for claim 2, in Hall (page 3, claim 13), there is a suggestion for the administration of at least two vaccines to one patient by the statement that “at least two different vaccines are separately and concurrently administered to the intended recipient with separate adhesive bandages being applied to each vaccination site.” To a person having ordinary skill in the art, with the teachings of Hall and Walsh, it would be obvious that each immunization will have its own common indicia in order to distinguish one immunization from another. This is the purpose of the immunization identification system. And again the motivation for this immunization identification method is for the tracking of more than one immunization to avoid medical error.

In regards to claim 8, “the first and second indicia are first and second colors.” Hall (page 2, claims 1-3) teaches that different forms of indicia, including color, are used to identify different vaccines.

In regards to claim 9, Hall does not teach of the series of stickers being applied to the home chart of the patient, but Walsh (column 34, lines 7-11 and column 33, lines 65-67), as mentioned above with claim 3, teaches of a “patient treatment chart” to which

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corresponding labels are applied. To a person having ordinary skill in the art, the “patient treatment chart” would be synonymous to “the home chart of the patient” since they perform the same function of medication record keeping. It would be obvious to apply the teachings of Walsh to those of Hall so that a patient can apply one label of a series of labels to his own home chart in order to keep track of his own different immunizations.

7. Claims 4, 5, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall and Walsh as applied to claim 1 or claim 7 above, and further in view of West et al (US 2002/0162261).

In regards to claims 4 and 5, Hall does not teach of providing a color on the immunization vial. Walsh (column 34, lines 1-6) teaches that labels are applied to the drug containers for identification purposes. In West et al (page 4, claims 8-9), it is taught that similar color-coded identification stickers are placed on drug containers and on their caps as well. It would be obvious to apply the teachings of Walsh and West to those of Hall in order to properly identify medication containers and to avoid medical error.

In regards to claim 10, Hall does not teach of providing indicia on the immunization vials. As mentioned by Walsh above, labels are applied to the drug containers for identification purposes. And West et al above, teaches that similar color-coded identification stickers are placed on drug containers and on their caps as well. Also, as stated above in Hall (page 3, claim 13), there is support for the administration of at least two vaccines to one patient by the statement that “at least two different vaccines are separately and concurrently administered to the intended

recipient with separate adhesive bandages being applied to each vaccination site.” It would be obvious to apply the teachings of Walsh and West to Hall so that different immunization indicia labels are applied to different immunization vials. The motivation for this is to track the different medications, or immunizations, administered to a patient and to avoid medical error.

### ***Response to Arguments***

8. Applicant's arguments, with regards to claims 1-3 and 6-9, filed on December 18, 2007, have been fully considered but they are not persuasive.

9. On page 9 of the Applicant's response, in regards to claims 1-3 and 6-9, applicant argues that the combination of Hall and Walsh fails to meet each of the limitations of the present invention. Applicant argues that Hall merely identifies the application of an adhesive bandage to a vaccination site and that although the Examiner claims that the bandage disclosed in Hall displays indicia that identify the vaccine that was administered, it fails to identify and correlate all of the information which the present method claims achieve. The Examiner respectfully disagrees with the Applicant's arguments because the method claims do not positively recite what is “achieved” by the invention. Since the claimed method would have been obvious to a person having ordinary skill in the art in light of the collective teachings of Hall and Walsh, whatever the claimed method is able achieve, such would have naturally flow from the teachings of Hall and Walsh. Also, Applicant states that “although the Examiner claims that the bandage disclosed in **Hall** displays indicia that identify the vaccine that was administered, **it** fails to identify and correlate all of the information which the present

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method claims achieve.” From this statement alone, Examiner agrees that Hall does not identify and correlate all the information of the present method claims. However, the rejection is NOT based on 35 USC §102, but rather is based the combination of Hall and Walsh in a 35 USC §103 rejection to correlate all the information that the present method claims teach.

10. On page 9, Applicant argues that corresponding adhesive-backed strips have the same color. Hall teaches adhesively-backed strips (paragraph [0013]) and color respective to different vaccines since *indicia identify the vaccine* (claim 12). Walsh teaches a “plurality of identical patient identifier carrying labels” that can be applied throughout the immunization identification method (column 33, lines 65-67 to column 34, lines 1-11). In a combination of Hall and Walsh, it would have been obvious that the strips would have the same color in order to discern one immunization from another based on color.

11. On page 10, Applicant argues that the present invention goes beyond merely identifying the type of immunization administered to a patient and placing such records in a chart. Each of these stickers are used to provide readily available identification of not only which vaccination has been administered to a patient, but also where it was administered, by route it was administered, from which vial it was administered, and then document all such information in a plurality of documenting means. Thus, this claimed invention solves a long-felt need, that is, inadvertent mistakes that happen in doctor offices for various reasons, as described in pages 1-2 of the Specification. Examiner agrees that inadvertent mistakes will be avoided in doctors’ office for the



above reasons. However, the combination of Hall and Walsh would achieve the same desired result of avoiding inadvertent mistakes and the above documenting techniques would have been obvious in the art in light of the teachings of the Hall and Walsh. As for said long-felt need, there is no long-felt need since such documenting techniques have been known in the prior art and therefore, there is long-felt need (i.e. problem) to be solved.

12. On page 10, Applicant argues that Applicant's claimed invention does not meet the obviousness tests of KSR: merely demonstrating that each element of a combination is known in the prior art does not constitute obviousness. Examiner agrees with the above statement of KSR that merely demonstrating that each element of a combination is known in the prior art does not constitute obviousness. However, there is a strong motivation to combine the references of Hall and Walsh and as such, such a combination would have been obvious to a person having ordinary skill in the art in order to solve the problem of inadvertent mistakes in doctors' offices.

13. On page 11, Applicant argues that the modification of Hall in view of Walsh, as suggested by the Examiner, still fails to combine the claimed steps in an obvious manner in that the application of the adhesive-back stickers coordinates as each sticker from the same strip is applied to a syringe, an injection site after the injection, and the medical chart of the patient. However, Hall does teach the application of a sticker after injection (page 2, claim 11). Walsh teaches the application of a sticker to a syringe and a sticker to a medical chart from the same strip (column 33, lines 65-67 to column 34, lines 1-11). It would have been obvious to a person having ordinary skill in the art to

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combine the teachings of Hall and Walsh to achieve the same results of immunization identification, as that of the Applicant.

14. The affidavit under 37 CFR 1.132 filed on 12/18/2007 is insufficient to overcome the rejection of claims 1-3 and 6-9 based upon Hall and Walsh as set forth in the last Office action. While Examiner agrees with Dr. Koob, Dr. Otteman, and Ms. Otteman in saying that applicant's immunization method is valuable and provides benefits to the medical field by increasing efficiency and improving documentation of immunizations; however, these benefits would naturally flow from the combination of teachings of Hall and Walsh which disclose the claimed process steps.

### ***Conclusion***

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571)270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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